Study of Chemical and Radiation Risk Assessment Methods for the United States Environmental Protection Agency and the United Kingdom Environment Agency

By

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I. Introduction

The U.S. Environmental protection Agency (U.S. EPA) and the UK Environment agency (EA) issued models for chemical risk assessment that are generally consistent with the agencies' radiation risk assessment models. EPA has issued the Regional Screening Level (RSL) calculator that is consistent with the Preliminary Remediation Goals (PRG) calculator. The EA issued Contaminated Land Exposure Assessment (CLEA) and The Radioactively Contaminated Land Exposure Assessment Methodology (RCLEA) that use similar modeling approaches. This paper presents the two agencies' methodologies for chemical and radiation risk assessment models.

II PRG and RSL

2.1 Preliminary Remediation Goal (PRG)

Preliminary Remediation Goals for Radionuclide Contaminants at Superfund Sites (PRG) is an electronic calculator developed by the U.S. Environmental Protection Agency (U.S. EPA). The PRG calculator presents risk-based standardized exposure parameters and equations that should be used for calculating radionuclide PRGs for residential, commercial/industrial, and agricultural land use exposures from soil, tap water, air and biota (Figure 1).

The calculator also presents PRGs to protect groundwater, which are determined by calculating the concentration of radioactively contaminated water leaching from radioactively contaminated soil to groundwater that will meet maximum contaminant levels (MCLs) or risk-based concentrations. Calculated PRGs can be produced generically (considered to be protective for humans, including the most sensitive groups) or using site-specific data for 1255 radionuclides in the PRG calculator, which may be found at: https://epa-prgs.ornl.gov/radionuclides/. The PRG calculator was first issued in 2002 and last updated in 2017. [1]

The U.S. EPA also issued the Dose Compliance Concentrations for Radionuclide Contaminants at Superfund (DCC) calculator in 2004. The DCC calculator is similar to the PRG calculator for demonstrating compliance with dose-based regulations. PRG and DCC are the same, except PRG uses slope factors (risk coefficients) over a period of exposure (e.g., 26 years for resident at the contaminated site) to provide concentrations for a target risk level while DCC uses dose conversion factors for a period of one year for a target dose limit. The PRG and DCC calculators are consistent to allow for consistent protective assumptions when complying with

the 10^{-4} to 10^{-6} risk range and dose based standards as Applicable or Relevant and Appropriate Requirements (ARARs). The DCC calculator may be found at:https://epa-dccs.ornl.gov/. [2]

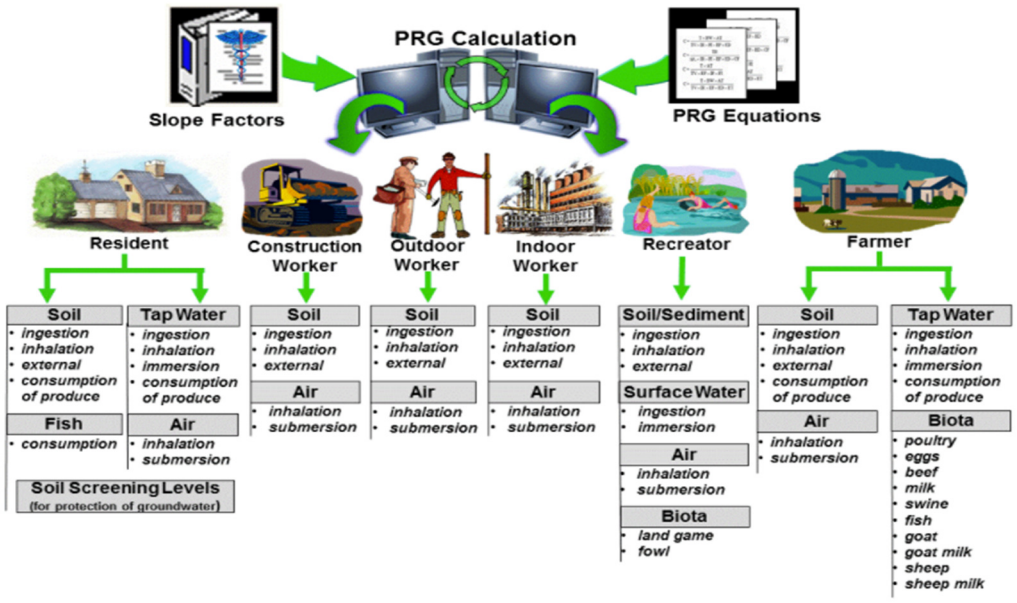

Figure 1: PRG calculator.

2.1.1 PRG Exposure Pathways and Scenarios:

Scenario/ Land use	Media
Resident	Soil, air, 2-D external exposure, tap water, and fish
Composite worker	Soil, air, 2-D external exposure
Outdoor worker	Soil, air, 2-D external exposure
Indoor worker	Soil, air, 2-D external exposure
Construction worker—standard unpaved road vehicle traffic (site-specific only)	Soil, air, 2-D external exposure
Construction worker—wind erosion and other construction activities (site-specific only)	Soil, air, 2-D external exposure
Recreator (site-specific only)	Soil, air, 2-D external exposure, surface water, game and fowl
Farmer	Air, biota direct, combined soil and biota, combined water and biota, biota from both soil and water
Soil to groundwater	Soil
Cover Layer	May be added to soil or 2D for shielding from external exposure

2.2 Regional Screening Levels (RSL)

The U.S. EPA developed the Regional Screening Levels (RSL) for Chemical Contaminants at Superfund Sites electronic calculator for chemicals in soil, water, and air (Figure 2). The RSL calculator uses standardized equations that combine exposure information assumptions with EPA toxicity data to produce conservative risk-based concentrations. The RSL website includes generic tables for several scenarios. The RSL calculator can perform site-specific screening using a combination of user-defined and default input variables and may be found at: https://www.epa.gov/risk/regional-screening-levels-RSL [3].

The RSL calculator is almost identical to the EPA Regional Removal Management Levels for Chemicals (RMLs) calculator for chemical risk assessment for emergency and time-critical removal actions, which may be found at: https://epa-rals.ornl.gov/. The RSL and RML are the same model with different interfaces to allow for different target default risk levels. In the RSL, cancer target risk is 1×10^{-6} and noncancer is a hazard index of 1; in the RML, the cancer target risk is 1×10^{-4} and the hazard index is 3. The RSL and RML have different risk targets to reflect the different roles of the long-term remedial and shorter-term removal programs.

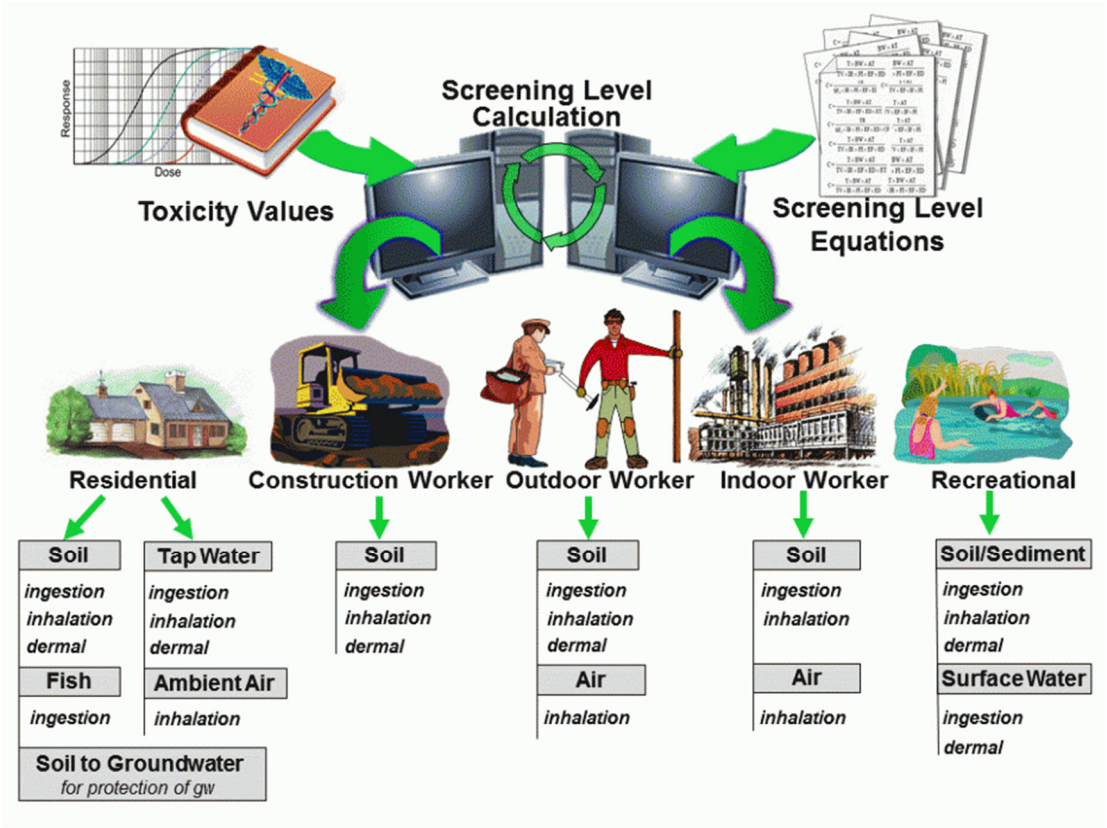

Figure 2: RSL Calculator.

2.2.1 RSL Exposure Pathways and Scenarios:

Scenario/ Land use	Media
Resident	Soil, air, tap water, and fish
Composite worker	Soil, air,
Outdoor worker	Soil, air,
Indoor worker	Soil, air,
Construction worker—standard unpaved road vehicle traffic (site-specific only)	Soil, air,
Construction worker—wind erosion and other construction activities (site-specific only)	Soil, air,
Recreator (site-specific only)	Soil, air, surface water, game and fowl
Farmer	Scenario not included
Soil to groundwater	Soil

2.3 Key similarities between the PRG and RSL methodologies

- PRG and RSL are both deterministic.
- PRG and RSL have resident, indoor worker, outdoor worker, composite worker, construction worker, recreator, and soil to groundwater scenarios. The scenarios have consistent default input parameters for soil ingestion and inhalation.
- PRG and RSL have additive cancer risks. Both have default target of 1×10^{-6} for each contaminant.
- PRG and RSL are both online calculators found at the EPA website.

2.4 Key differences between the PRG and RSL methodologies

- RSL does not include produce or farm animal consumption that are in the PRG.
- RSL does not include farmer scenario.
- RSL uses unit inhalation risk while PRG uses inhalation slope factors.
- RSL accounts for dermal (skin absorption) while PRG accounts for external (gamma) exposure.
- RSL addresses noncancer risks, including total uranium; PRG does not address noncancer risks.

III RCLEA and CLEA

3.1 The Radioactively Contaminated Land Exposure Assessment Methodology (RCLEA)

RCLEA is a mathematical model developed by Quintessa in support of the Part IIA regulatory regime of the UK. Government Department for Environment, Food and Rural Affairs (DEFRA) for managing contaminated land in the UK. RCLEA is an Excel file with a collection of worksheets that contain all input data and results. The default input data is protected against any change, and the equations are hidden (Figure 3). RCLEA considers a set of 47 radionuclides that are commonly found in radioactively contaminated sites in the UK. It can perform screening assessments of individual radionuclides or mixtures of radionuclides. The model can be used for generic or site-specific assessments. RCLEA was issued in 2003 and may be downloaded at: http://www.rclea.info/index.htm. [4]

Figure 3: RCLEA spreadsheet.

3.1.1 RCLEA Exposure Pathways and Scenarios:

Land Use	• Residential with Home-Grown Produce • Residential without Home-Grown Produce • Allotments • Commercial/Industrial
Building types	• Timber • Concrete Brick
Receptor	• Infant (1 year old) • Child (10 year old) • Adult (>17 year old)
Receptor Sex	• Male • Female
Exposure Pathways	• Whole body external irradiation • Soil ingestion • Dust ingestion • External irradiation of the skin from dermal contact • Dust inhalation • Consumption of homegrown produce • Consumption of soil associated with home grown produce • Inhalation of Rn-222 gas indoors

3.2 Contaminated Land Exposure Assessment (CLEA)

CLEA is also a mathematical model developed by Quintessa in support of the Part IIA regulatory regime of the DEFRA for managing contaminated land in the UK. The CLEA model can perform a generic or site-specific assessment to assess whether a measured chemical concentration in soil poses a potential risk to human health for those live, work or play on

contaminated sites over long periods of time. CLEA may be downloaded at:

https://www.gov.uk/government/publications/contaminated-land-exposure-assessment-clea-tool.

[5]

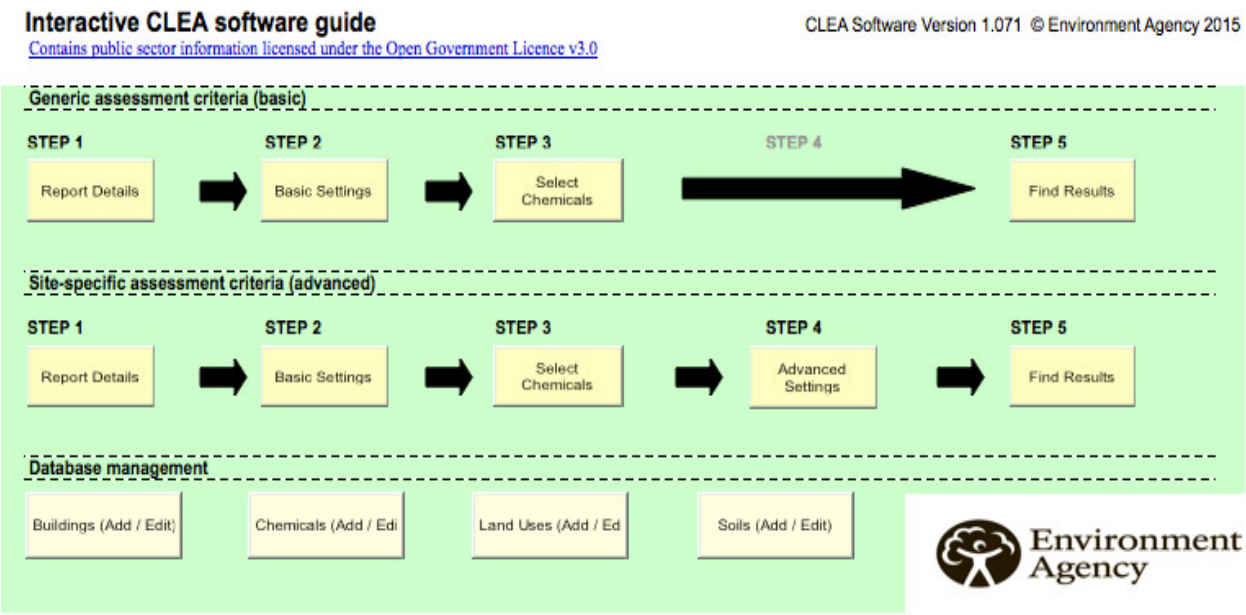

Figure 4: CLEA spreadsheet.

3.2.1 CLEA Exposure Pathways and Scenarios:

<table>
<tr><td>Land Use</td><td>• Residential with Home-Grown Produce
• Residential without Home-Grown Produce
• Allotments
• Commercial/Industrial</td></tr>
<tr><td>Building types</td><td>• Timber
• Concrete Brick</td></tr>
<tr><td>Receptor</td><td>
<table>
<tr><th>Class</th><th>Age (years)</th><th>Exposure duration (years</th></tr>
<tr><td>1</td><td>0-1</td><td>1</td></tr>
<tr><td>2</td><td>1-2</td><td>1</td></tr>
<tr><td>3</td><td>2-3</td><td>1</td></tr>
<tr><td>4</td><td>3-4</td><td>1</td></tr>
<tr><td>5</td><td>4-5</td><td>1</td></tr>
<tr><td>6</td><td>5-6</td><td>1</td></tr>
<tr><td>7</td><td>6-7</td><td>1</td></tr>
<tr><td>8</td><td>7-8</td><td>1</td></tr>
<tr><td>9</td><td>8-9</td><td>1</td></tr>
<tr><td>10</td><td>9-10</td><td>1</td></tr>
<tr><td>11</td><td>10-11</td><td>1</td></tr>
<tr><td>12</td><td>11-12</td><td>1</td></tr>
<tr><td>13</td><td>12-13</td><td>1</td></tr>
<tr><td>14</td><td>13-14</td><td>1</td></tr>
<tr><td>15</td><td>14-15</td><td>1</td></tr>
<tr><td>16</td><td>15--16</td><td>1</td></tr>
<tr><td>17</td><td>16-65</td><td>49</td></tr>
<tr><td>18</td><td>65-75</td><td>10</td></tr>
</table>
</td></tr>
<tr><td>Receptor Sex</td><td>• Male
• Female</td></tr>
<tr><td>Exposure Pathways</td><td>Oral:
• Direct soil ingestion
• Direct dust ingestion
• Consumption of homegrown produce
• Consumption of soil attached to homegrown produce
Dermal:
• Indoor dermal uptake
• Outdoor dermal uptake
Inhalation:
• Indoor dust inhalation
• Outdoor dust inhalation
• Indoor vapor inhalation
• Outdoor vapor inhalation</td></tr>
</table>

3.3 Key similarities between the RCLEA and CLEA methodologies

- Uniform contamination to a depth of 1 m from the surface.
- Same land uses: Residential with Home-Grown Produce, Residential without Home-Grown Produce**,** Allotment, and Commercial/Industrial.
- Same building types.
- Same exposure pathways, with the exception of pathways associated with volatile contaminants and skin absorption.
- Both do not consider the ingestion of animal products.
- Default input parameters, soil consumption, occupancy factors, consumption rates, breathing rates, body weight, mass loading factors, etc. Age-dependent data has been obtained from CLEA. Additional data have been selected to be consistent with CLEA as far as possible.
- Similar equations for calculating the potential intake of radionuclides and chemical in contaminated soil.
- Both models are implemented in a Microsoft Excel® workbook application.

3.4 Key differences between the RCLEA and CLEA methodologies

- CLEA (Soil Guideline Value) SGVs for non-radioactive contaminants are contaminant-specific and not additive, while the radiation doses from multiple radionuclides are additive and compared with a single exposure criterion.
- The RCLEA methodology is deterministic in nature in comparison to CLEA's probabilistic approach.

- The CLEA methodology includes data for 18 different age groups, while RCLEA includes only three (Infant, Child and Adult). The number of age groups has been reduced in the RCLEA methodology to reflect the dose coefficient recommendations of the International Commission on Radiological Protection (ICRP).
- RCLEA includes two additional exposure pathways due to the potential of radionuclides to impact on human health while external to the body:

  - whole body external irradiation from contamination at a distance and

  - irradiation of the skin from direct contact with contaminated material.
- Volatilization and absorption through skin is not considered in RCLEA methodology, while CLEA consider volatilization and absorption of chemicals through skin.
- The RCLEA methodology adopts a single soil type, while CLEA adopts several soil types with one default soil type (sandy loam soil).
- RCLEA adopts a higher concentration of atmospheric respirable particulates in comparison with CLEA.

IV Discussion

The two U.S. EPA models, PRG and RSL, are both deterministic and internet-based calculators. The UK EA models, RCLEA and CLEA, are both implemented in a Microsoft Excel® workbook application. The RCLEA is a deterministic model while CLEA is probabilistic. PRG and RSL both have a target risk of $1x10^{-6}$ for each contaminant, whether it is radionuclide or chemical, which can be additive cancer risks. The U.S. EPA methodology is more practical when assessing mixed chemically and radioactively contaminated sites. There are number of reasons why EPA uses the same methods for chemical and radioactive contamination: 1) both contaminants are carcinogenic, 2) people ingest and inhale same amount of contaminated dust and food whether it is chemical or radioactive contamination, 3) dust gets resuspended the same whether it is chemically or radioactively contaminated, and 4) inorganic elements move through the subsurface whether they are radioactive or not. The US EPA uses "slope factors" instead of dose conversion tables to estimate cancer risk from radioactive contaminants. RCLEA and CLEA do not have the risk additives. The result of CLEA assessment is contaminant-specific and not additive, while RCLEA can add radiation doses from multiple radionuclides. The result of RCLEA and CLEA cannot be summed and compared to a specific limit. The UK EA methodologies could be used separately for mixed contaminated sites. In the UK, legislation is driven by European Union directives that divide radioactive and non-radioactive contaminated sites. PRG and RSL have similar scenarios (resident, indoor worker, outdoor worker, composite worker, recreator, construction worker, and soil to groundwater scenarios) except farmer scenario is not available in RSL. Similarly, RCLEA and CLEA use similar scenarios/ land uses (Residential with Home-Grown Produce, Residential without Home-Grown Produce**,** Allotment, and Commercial/Industrial). PRG and RSL have consistent default input parameters and

equations for calculating the potential intake of radionuclides and chemicals in contaminated soil. RCLEA and CLEA have the same approach. The U.S. EPA chemical model, RSL, and the UK EA chemical model, CLEA, consider skin absorption but do not consider this pathway for their radiation models, PRG and RCLEA. In general, the U.S. EPA and the UK EA models use consistent exposure pathways, with some exceptions, that take into consideration the differences between the chemical and radioactive properties of the elements.

V Conclusion

The U.S. EPA (PRG and RSL) and UK EA (RCLEA and CLEA) have consistent methodologies for chemical and radiation risk assessment. The U.S. EPA's longstanding policy is that similar models should be used for the chemical and radionuclide risk assessments so that the results are consistent with summed assessments. The UK EA, in general, uses consistent methodologies when dealing with chemically and radioactively contaminated lands.

References:

1. U.S. EPA. [2002 (last updated in 2017)]. *Preliminary Remediation Goal (PRG).* Retrieved from http://epa-PRG.ornl.gov/cgi-bin/radionuclides/rprg_search.
2. U.S. EPA. [2004 (last updated in 2017)]. *Dose Compliance Concentration (DCC).* Retrieved from http://epa-dccs.ornl.gov/cgi-bin/dose_search.
3. U.S. EPA. (2017). *Regional Screening Levels (RSL) for Chemical Contaminants at Superfund Sites electronic calculator.* Retrieved from https://epa-PRG.ornl.gov/cgi-bin/chemicals/csl_search.
4. UK DEFRA. (2003). *The Radioactively Contaminated Land Exposure Assessment Methodology (RCLEA).* Retreived from https://www.gov.uk/government/publications/rclea-software-application.
5. UK DEFRA. (2009). CLEA Software, version 1.05. Bristol: Environment Agency. Retrieved from https://www.gov.uk/government/publications/contaminated-land-exposure-assessment-clea-tool.